Op-Ed: The Commission presents the EU's Pharmaceutical Strategy: a paradigm shift?

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Presenting a Pharmaceutical Strategy for Europe in the middle of a pandemic has moved the European Commission into the spotlight in an area that otherwise is probably more of a niche topic in the EU law and policy community. Still, it should be clarified that the Pharmaceutical Strategy is not a reaction to the COVID-19 crisis: many of the action points contained in the Strategy can be traced back to the mission letter that President von der Leyen provided Commissioner Kyriakides with in September 2019. However, while reforms of the regulatory framework were to be expected, the COVID-19 pandemic has certainly been a catalyst for the Commission initiatives in this area.

The key action points of the Pharmaceutical Strategy are not surprising for those that have followed the debates in EU pharmaceutical law and policy in the recent years. To summarise the areas of concern: accessibility of medicines; antimicrobial resistance (AMR); pharmaceutical industry competitiveness and innovation facilitation; regulatory efficiency; supply chain dependence; and environmental risks. These topics were also raised in the 2017 European Parliament Resolution on options for improving access to medicines and the 2018 European Parliament Resolution on Antimicrobial Resistance.

The first challenge identified in the Strategy is accessibility to medicine, and the Commission has identified several aspects that require improvement. First of all, the Commission made clear that it sees the need to foster and steer innovation in areas of currently unmet medical need – this refers to the lack of medicines for certain rare diseases as well as neglected patient groups like children, senior citizens and pregnant or breastfeeding women. This also became evident in the evaluation of the respective legal measures currently in place, as published in August. Without regulatory interference there is little economic incentive to develop these products and the currently existing incentives have been successful only in certain therapeutic areas. An Inception Impact Assessment has

already been published for the revision. Additionally, a problem of the current regulatory framework is that medicines, even though they obtained EU-wide marketing authorisations, are not accessible in all Member States because companies may choose not to market their product in certain countries. Here, the Commission considers making incentives conditional on improved accessibility.

Other accessibility problems concern the current debate surrounding excessive pricing of pharmaceuticals. The competence for pharmaceutical pricing as an important component of the organisation of national healthcare systems lies with the Member States. Therefore, the Commission in the Pharmaceutical Strategy mostly focusses on strengthening cooperation between the Member States and also aims to make the cost of medicines development more transparent. It also wants to use public procurement practices and the enforcement of competition law to address this issue. Finally, the Strategy in this context refers to the already proposed Health Technology Assessments (HTA) Regulation, which first met resistance in the Council of the European Union but now seems to have been reinvigorated by the pandemic, and aims to strengthen the cooperation of the Member States in establishing the added value of a new medicine.

One issue that was already recognised before the pandemic, but which has been magnified by COVID-19, is medicines shortages due to interruptions in the supply chain. Europe is currently highly dependent on the production of medicines and their active ingredients in third-countries and this has already led to shortages in the past. The Commission in the Strategy announced that a study to assess the causes of shortages is underway and that the legislative framework could potentially be reviewed in order to place more responsibilities on the industry to ensure stable supply. In this regard, the Strategy is not as pronounced as some might have expected in moving pharmaceutical production back to Europe.

Along with these more patient-centred accessibility issues, the Commission also wants to support innovation and competitiveness of the EU pharmaceutical industry. In this regard, the vision of the Strategy is very focussed on digitalisation and the creation of the European Health Data Space to be established until 2025. Furthermore, taking into account the Intellectual Property Action Plan, the supplementary protection certificate system will be streamlined. Main areas of innovation like gene and cell therapies, personalised medicines and medicines containing or consisting of GMOs should be supported through revising the regulatory frameworks for innovative clinical trials and the use of real-world data in the assessment process. Overall, the strategy in terms of the regulatory procedures in place does not propose radical changes, but more the increasing of regulatory flexibility in the face of technological and scientific progress.

Finally, the strategy promises actions with regard to the global threat of antimicrobial resistance, environmental risks caused by pharmaceutical production and disposal, as well as maintaining a strong European position in global regulatory cooperation. Thus overall, the Strategy contains few surprises and it is also not the start of a

revolutionary overhaul of the regulation of pharmaceuticals in the EU. This is a testament to the efficiency of the framework in place. However, the Pharmaceutical Strategy does address existing problems for patients by promising to fine-tune incentive structures and revise regulatory approaches to benefit from new technologies. The Strategy has been welcomed by the European Parliament, however, the announced reassessment of the incentive schemes has raised criticism in the industry.

From a more general EU law perspective the Pharmaceutical Strategy is interesting, as it indicates a shift from a pharmaceutical policy that is driven by the facilitation of the free movement of goods and strongly emphasised the regulation of risks with regard to medicinal products, to questions of accessibility of the products for patients and the steering of innovation via incentive schemes. This is not to say that the EU was not active in these areas before, as the Regulations for orphan medicinal products and paediatrics or the proposed HTA Regulation show. However, it is remarkable how little internal market and risk regulation concerns feature in the Strategy and how pronounced the new patient-centred approach is presented.

The legal basis for the adoption of EU legislation in the field of pharmaceuticals is to be found in the internal market provision of Article 114 TFEU, sometimes in conjunction with Article 168(4) TFEU providing for the adoption of '(m)easures setting high standards of quality and safety for medicinal products and devices for medical use'. This is to be contrasted with the organisation of health care systems which remains the competence of the Member States, as enshrined in Article 168(7) TFEU. The focus on accessibility in the Strategy and the rethinking of incentives to steer innovation is thus by no means self-evident and the Commission is also careful to emphasise that in many planned initiatives that the EU action will be limited to supporting Member State cooperation. Similar competence questions are raised in the debate surrounding the European Health Union. However, where the Pharmaceutical Strategy is indeed seen as a first step towards the reorientation of the focus of pharmaceutical policy, it is a paradigm shift and maybe even an indicator of a maturing of the regulatory framework.

With regard to the Pharmaceutical Strategy a key question will be whether and in how far this reorientation will receive the support of the Member States. Just to put the re-gained enthusiasm for EU health competences into context, in 2017 the European Commission in its White Paper on the future of Europe in one presented scenario had included public health as an area where the EU 'is perceived as having more limited added value, or as being unable to deliver on promises'. Looking at the history of market integration for pharmaceuticals and also the resistance that the HTA Regulation proposal has met in the Council before the pandemic, health law in general and pharmaceutical law in particular are politically and economically sensitive areas for the Member States. The question where competences regarding medicines accessibility and pricing should be allocated is complex. However, it is clear that the issues that the Commission raises in the Pharmaceutical Strategy are far more connected to the organisation of the healthcare systems of the Member States than the traditional market and

risk policy in the pharmaceutical sector. In the State of the Union Address, President von der Leyen has said that: 'it is clearer than ever that we must discuss the question of health competences.' Therefore, the progress of the initiatives proposed in the Pharmaceutical Strategy might provide some insights into the prospect of the Unions repositioning in health law in general.

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